



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0500]

Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; requests for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a request for additional comments on the chemistry, manufacturing, and control (CMC) information that a sponsor of an investigational new drug application (IND) should provide in its IND in order to meet regulatory requirements when commercially available foods or dietary supplements containing live biotherapeutic products (LBPs) are used as investigational new drugs in early phase clinical trials. The request for additional comments on the CMC information is related to the guidance entitled, “Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry,” dated February 2012 (February 2012 guidance).

DATES: Submit either electronic or written comments on the requested CMC information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the February 2012 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the requested CMC information to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a request for additional comments on the CMC information that a sponsor of an IND should provide in its IND in order to meet the requirements under § 312.23 (21 CFR 312.23), when commercially available foods or dietary supplements containing LBPs are subject to study as investigational new drugs in early phase clinical trials.

In the Federal Register of February 21, 2012 (77 FR 9947), FDA announced the publication of a final guidance entitled “Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry,” dated February 2012. The guidance provides IND sponsors with recommendations regarding CMC information

that should be included in IND submissions for early clinical trials with LBPs, including LBPs lawfully marketed as foods or dietary supplements in the United States and proposed for clinical uses regulated under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance also outlines the Drug Substance and Drug Product information that should be provided in the CMC section of an IND to meet the requirements under § 312.23 and to support proceeding to clinical evaluation of an LBP in human subjects.

II. CMC Information

FDA is considering modifying the February 2012 guidance to address the CMC information that should be provided in an IND, under certain conditions. Specifically, FDA is considering whether to revise the guidance to address when the label on the commercially available product(s) would be considered adequate to satisfy the requirement for CMC information under § 312.23. For example, we are considering whether the label would be adequate to satisfy the CMC information when the following conditions are met: (1) The LBP product that is proposed for investigational use is a commercially available food or dietary supplement; (2) the investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of risk) associated with the use of the food or dietary supplement; (3) the investigation is not intended to support a marketing application for a drug claim for the food or dietary supplement; and (4) the investigation is conducted in compliance with the requirements for INDs (part 312), the requirements for review by an institutional review board (21 CFR part 56), and with the requirements for informed consent (21 CFR part 50). FDA is seeking public comment on this issue.

III. Comments

Interested persons may submit either electronic comments regarding the requested CMC information to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the February 2012 guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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